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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,298	06/07/2006	Minoru Yoshida	20214-002US1	1652

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EXAMINER	
HEARD, THOMAS SWEENEY	
ART UNIT	PAPER NUMBER
1654	

NOTIFICATION DATE	DELIVERY MODE
03/19/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	10/561,298	YOSHIDA ET AL.	
	Examiner	Art Unit	
	THOMAS S. HEARD	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 11* is/are pending in the application.

4a) Of the above claim(s) *11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/18/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claim 11 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/17/2008.

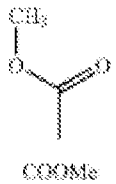
The Applicants Amendments to the claims received on 2/17/2009 is acknowledged. Claim(s) 1-9 and 11 are pending. Applicants have amended claim(s) 1 and 9. Claim(s) 11 is/are withdrawn. Claims 1-9 are hereby examined on the merits.

Claim Objections

Claim 1-9 is objected to because of the following informalities: the phrase 'represent,' while understood should be stated in a manner that R_{11}, R_{21}, R_{31}, and R_{41} is a hydrogen, a linear alkyl group, etc…, rather than "represent." Appropriate correction is required.

In Claim 1, and text line 9, R_41 needs correction to R_{41} to be consistent with the other R variables.

Claim 2 is objected to as the substituents are not clearly labeled. For example,



is not clearly understood. The COOMe is offset from the drawn structure but could appear to be bonding to the oxygen, which is chemically impossible. However, in Figure 2 of the specification, the COOMe appears to be the abbreviation for the

structure. It would be clear if it is intended to be an abbreviation that the abbreviation be offset to the side and away from the intended bond indicator.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 1, the term “carry” is not understood. The functional groups claimed are chemical entities that are covalently attached. The term “carrying” is not understood in the normal context of the chemical language of Claim 1.

In Claim 1, the phrase "a range of numbers that enable the compound to have HDAC inhibitory activity" is not understood. The range of numbers is not specified in the claim to indicate what the specific range of numbers would be to enable that intended activity.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

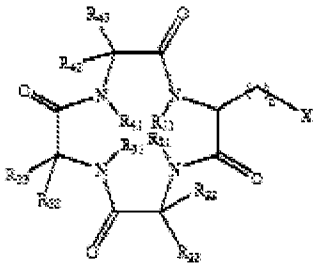
Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was

not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

The factors considered in the Written Description requirement are (1) level of skill and knowledge in the art, (2) partial structure, (3) physical and/or chemical properties, (4) functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the (5) method of making the claimed invention.

In the instant case, the claims are drawn to compounds of the following structure:



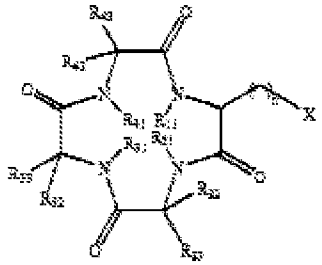
.

(1) Level of skill and knowledge in the art:

The level of skill to practice the art of the instantly claimed invention is high with regard to synthesis, isolation, determination and characterization of the compounds structure, as well as the assays for determining activity and efficacy in the intended use.

(2) Partial structure: (3) Physical and/or chemical properties: and (4) Functional characteristics:

The partial structure is that of Formula (I)



where the various R groups can be a plurality of unrelated chemical structures attached to the core of Formula (I). The physical properties of the molecules are that of HDAC inhibition, known in the prior art as anti-angiogenesis inhibitors and anti-tumor agents as studies in mice, Saito A, "A synthetic inhibitor of histone deacetylase, MS-27-275, with marked in vivo antitumor activity against human tumors," Proc Natl Acad Sci U S A. 1999 Apr 13;96(8):4592-7.

(5) Method of making the claimed invention:

Chemical synthesis.

As stated supra, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that Claim 1 is a broad generic, with respect to all possible compounds encompassed by the claims. The possible structural variations are limitless to any class of compound where aspects of the molecule, X in the instant case, is claimed by what it does rather than what it is, i.e., X represents a structural component having a structure that can coordinate with the zinc porisi0oned at the active center of histone deacetylase.

It must not be forgotten that the MPEP states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. "MPEP § 2163.

Here, though the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond compounds disclosed in the examples in the specification. There are 9 examples and while having written description for these examples identified in the specification tables there is insufficient description of a common core structure for X that would allow one of skill in the art to practice the invention as claimed. “X is a structural component having a structure” is an apparent substructure of X, and the whole of X is not described beyond what it does. In order to inform the artisan of what constitutes X in terms of function, and also to show possession, a common core, or a definite partial structure, needs to be disclosed such that a structure and function correlation can be made. At present, and within the specification, no such common core structure has been disclosed. Only a function to an unknown structure is made. Finally, how one can make a cyclic structure with R_{21} and R_{22}, or R_{22} and R_{23}, etc…, with only a chain length of 1 carbon is not described. The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope

the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

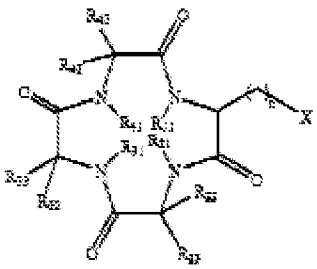
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoshida et al, EP 1010705A1 (from Applicant's IDS).

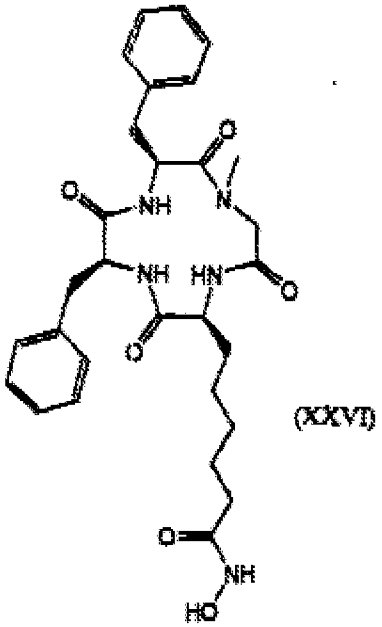
The instant invention is drawn to compounds of the formula



where R_{11}, R_{21}, R_{31}, and R_{41} independently represent a hydrogen or methyl group; R_{22}, R_{23}, R_{32}, R_{33}, R_{42}, and R_{43} independently represent any one of hydrogen, a linear alkyl group comprising 1 to 6 carbons, a linear alkyl group comprising 1 to 6 carbons to which a non- aromatic cyclic alkyl group or a substituted or

unsubstituted aromatic ring is attached, a non- aromatic cyclic alkyl group, or a non-aromatic cyclic alkyl group to which a non-aromatic cyclic alkyl group or a substituted or unsubstituted aromatic ring is attached; n can be selected from a range of numbers that enable the compound to have HDAC inhibitory activity; and X represents a structural component having a structure that can coordinate with the zinc positioned at the active center of histone deacetylase.

Yoshida et al discloses the following compound



(XXVI)

where R_{11}, R_{21}, R_{31}, R_{41}, R_{42}, and R_{43} is H, R_{32} and R_{23} is H, and R_{33} and R_{22} is an alkyl of 1 carbon length substituted with an unsubstituted aromatic, n is 4, and X is C(0)NHOH, all readable on Claim 1. The functionality of X as taught by Yoshida et al must function as a structural component having a structure that can coordinate with the zinc positioned at the active center of histone deacetylase because the compounds are disclosed as being histone deacetylase inhibitors. Further, Claims 3-9 are also

readable on Claim 1 because the preamble of the claims, such as a histone deacetylase inhibitor comprising the compound of claim 1 as an active ingredient, or a tubulin deacetylase inhibitor comprising the compound of claim 1 as an active ingredient, or an apoptosis inducer comprising the compound of claim 1 as an active ingredient; or a differentiation inducer comprising the compound of claim 1 as an active ingredient, or an angiogenesis inhibitor comprising the compound of claim 1 as an active ingredient, cancer metastasis inhibitor comprising the compound of claim 1 as an active ingredient, is still the compound of Claim 1. The compound is disclosed as a pharmaceutical composition and is therefore, readable on Claim 9. The invention as claimed is anticipated by the prior art.

Conclusion

No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Prior art contained in the reference of record can be applied in the next office action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas S. Heard whose telephone number is (571) 272-2064. The examiner can normally be reached on 9:00 a.m. to 6:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anish Gupta/
Primary Examiner, Art Unit 1654

/Thomas S Heard/
Examiner, Art Unit 1654